

510(k) Summary  
for the  
Range Spinal System,

This safety and effectiveness summary for the Mesa Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

**1. Submitter :**

K2M, Inc.  
751 Miller Drive SE,  
Suite F1  
Leesburg, VA 20175

**Contact Person :**

Richard W. Woods  
K2M, LLC  
751 Miller Drive SE, Suite F1  
Leesburg, VA 20175  
Telephone: 703-777-3155

Date Prepared: May 07, 2008

**2. Tradename:**

Range Spinal System

**Common Name:**

Spine Fixation System

**Classification Name:**

Pedicle Screw Spinal System ( 21 CFR 888.3070(b)(1) )  
Spinal Interlaminar fixation orthosis ( 21 CFR 888.3050 )

**3. Predicate or legally marketed devices which are substantially equivalent :**

- Range Spinal System ( K2M, Inc.)
- Expedium (DePuy)

**4. Description of the device :**

The Range Spinal System is a top-loading, multiple component, posterior spinal fixation system which consists of pedicle screws, rods, hooks, and transverse connectors. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

**Materials:** The devices are manufactured from Ti6Al-4V ELI alloy per ASTM and ISO standards.

**Function:** The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the thoracic, lumbar and / or sacral spine.

**5. Intended Use:**

The Range Spinal System is a:

Non-cervical spinal fixation device intended for posterior, non-pedicle fixation for the following indications: degenerative disc disease ( DDD ) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies ); spondylolisthesis; trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures ( i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Mesa Spinal System is also intended for:

Non-cervical pedicle screw fixation for the following indications: trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures ( i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis ( grades 3 and 4 ) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum ) with removal of the implants after the attainment of a solid fusion.

**6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :**

The Range Spinal System was biomechanically tested and compared to the predicate systems and other currently marketed systems and performed equal to or better than these systems in ASTM testing to F1717. The design features and sizing of the components were also compared and the Range Spinal System found to be substantially the same as these systems. It is manufactured from the same FDA recognized materials and is indicated for the same intended uses as these systems. There are no significant differences between the Range Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

K2M, Inc.  
% Ms. Nancy Giezen  
751 Miller Drive, Southeast, Suite F1  
Leesburg, Virginia 20175

**MAY 19 2009**

Re: K081381  
Trade/Device Name: Range Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNH, MNI, KWP  
Dated: May 16, 2008  
Received: May 16, 2008

Dear Ms. Giezen:

This letter corrects our substantially equivalent letter of June 13, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
 Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K081381

## Indications for Use

510(k) Number: ~~K076229~~

Device Name: Range Spinal System

### Indications for Use:

Non-cervical spinal fixation devices intended for posterior, non-pedicle fixation for the following indications: degenerative disc disease ( DDD ) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies ); spondylolisthesis; trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures ( i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Non-cervical pedicle screw fixation for the following indications: trauma ( i.e. fracture or dislocation ); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis ( grades 3 and 4 ) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum ) with removal of the implants after the attainment of a solid fusion.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use       
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick R. Dyer for me  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K081381

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